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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,371	11/13/2001	Steinunn Baekkeskov	2307AA-043030US	1403

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/30/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,371

Applicant(s)

BAEKESKOV ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when ✓ the reference is to a prior application of a CPA assigned the same application number. The first sentence in the instant application names only two earlier applications, and states that the instant application is "related" to them.

The disclosure is objected to because of the following informalities:

✓ Reference citations at page 3, line 21; page 11, line 29; and page 17, line 12, are incomplete.

Appropriate correction is required.

✓ Claims 1-14 were cancelled and claim 15 was added by preliminary amendment.
Claim 15 is under examination.

✓ Claim 15 is drawn to a protein characterized in its natural state by a membrane-bound islet cell location, a molecular weight of 38 kD, an amphiphilic charge, and pl of from 5.4 to 6.1, and that specifically binds to autoantibodies.

35 U.S.C. 101 reads as follows:

✓ Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 15 recites "a protein" with various characteristics, but does not distinguish over the naturally-occurring protein, i.e., the

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protein as a product of nature. This rejection might be overcome by amending the claim to specify that the protein has been isolated or purified, for example. Applicant is cautioned against the introduction of new matter in amending the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is confusing because it recites a pI value for a membrane-bound protein in its "natural state." It would seem that the "natural state" of a membrane protein is within an intact membrane and it is not understood how one can measure or assign a pI value to a protein in that "natural state."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Since this application was filed as a continuation of application 08/937955 and was filed with a copy of the Declaration for application 08/048886 which had a filing date of April 16, 1993, this examination is carried out assuming that Applicant intends to claim and establish priority through a series of continuation applications to application 08/048886. Accordingly, for the purposes of this examination, claim 15 has been examined as if it has an effective filing date of April 16, 1993.

Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by Pak et al., Diabetologia 33:569-572, 1990, cited on PTO 892, attached. Pak et al. disclose detection of autoantibodies against human islet cells. See, e.g., page 570, column 2, "Detection of autoantibodies against islet cells." Human islet cells are deemed to anticipate the subject matter of claim 15 because claim 15 as currently drawn does not distinguish over islet cells that contain the naturally-occurring protein.

Claim 15 is additionally rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pak et al. as cited above. Pak

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et al. disclose a human pancreatic islet cell specific 38 kilodalton autoantigen that reasonably appears to be the same as, or only slightly different from, the 38 kD protein as instantly claimed, since it is detected in detergent-treated islet cell lysates and reacts with autoantibodies in diabetic patients. See, e.g., page 570-571, "SDS-PAGE and western immunoblotting" and page 571, second full paragraph.

Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roep et al., Lancet 337:1439-1441, 1991, cited on PTO 892, attached. Roep et al. disclose a 38 kD insulin-secretory-granule protein in diabetic patients that reasonably appears to be the same as, or only slightly different from, the 38 kD protein as instantly claimed, since it appears in recent-onset type 1 diabetic patients, is found in islet cells, and is associated with membranes (see, e.g., the Abstract, the Introduction, and page 1440, first full paragraph).

Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ko et al., Diabetologia 34:548-554, 1991, cited on PTO 892, attached. Ko et al. disclose a 38 kD islet cell protein from BB rats that reasonably appears to be the same as, or only slightly different from, the 38 kD protein as instantly claimed, since it can be isolated from islet cell lysates, but not from lysates of other cell types, and it binds autoantibodies from diabetic rats and humans (see, e.g., page 549, Metabolic labelling and immunoprecipitation and Differential Western blotting; page 550-551, Detection of antibody against a 38 kD islet cell protein).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is

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703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
June 27, 2003